OFFICIAL

PETITION UNDER 37 C.F.R. 1.181(a)
EXPEDITED PROCEDURE
EXAMINING GROUP 3738

PATENT
Attorney Docket No. 101.0084-01000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No.: 8295
Gary K. Michelson	)	
Serial No.: 09/921,844	)	Group Art Unit: 3738
Filed: August 3, 2001	)	Examiner: B. Snow
For: SPINAL IMPLANT SURFACE CONFIGURATION	)	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION UNDER 37 C.F.R. § 1.181(a)

In response to the Advisory Action dated April 23, 2004, Applicant petitions the Director to: (1) rescind the Examiner's requirement that Applicant cancel elected claims that the Examiner has improperly characterized as non-elected claims in response to the Examiner's final action, (2) rejoin claims improperly withdrawn by the Examiner, and (3) withdraw the finality of the last office action.

I. Background

In reply to the Restriction Requirement dated October 28, 2002 (the "Restriction Requirement"), Applicant elected independent claims 1, 131, and 219 drawn to Species 3, Figure 12. A copy of the Restriction Requirement is attached hereto as Exhibit A and a copy of Applicant's Reply to the Restriction Requirement is attached as Exhibit B. In the Office Action dated April 23, 2003 (the "April Office Action"), the Examiner affirmed Applicant's election and stated that claims 1, 131, and 219 "read on the elected species as indicated by applicant in paper No. 6." (April Office Action, page 2, paragraph 1). A copy of the April Office Action is attached hereto as Exhibit C.

In the April Office Action, the Examiner rejected independent claims 1, 131, and 219 under 35 U.S.C. § 112, second paragraph, for being indefinite because the Examiner did not understand the difference between the phrases "bone engaging structures" and "surface projections." (April Office Action, page 3, paragraph 1). The Examiner also did not understand how the terminology in claim 131 related to the orientation of the surface projections as claimed. (April Office Action, page 3, paragraph 2).

In Applicant's reply dated October 8, 2003 (the "October reply"), Applicant amended independent claims 1, 131, and 219 to delete the phrase "bone engaging structure," and amended claim 131 to replace the terminology regarding the orientation of the projections not understood by the Examiner. A copy of the October Reply is attached hereto as Exhibit D. These amendments overcame all of the Examiner's rejections under 35 U.S.C. § 112, second paragraph from the April Office Action.

In the Final Office Action dated January 7, 2004 (the "Final Office Action"), on his own accord without authorization from Applicant, the Examiner withdrew from consideration independent claim 131 and its dependent claims as "being drawn to a nonelected species." (Final Office Action, page 2, paragraph 2). A copy of the Final Office Action is attached hereto as Exhibit E. Fig. 12B, added pursuant to the Examiner's request, shows left and right facets as recited in claim 131. The Examiner did not restrict the embodiment of Fig. 12B as a separate species.

The Examiner also rejected dependent claims 43 and 247 (dependent from claims 1 and 219, respectively) under 35 U.S.C. § 112, second paragraph, as being indefinite because the Examiner did not understand the phrase "motion preserving device." (Final Office Action, page 5, paragraphs 1-2).

On March 26, 2004, Applicant requested the Examiner to rejoin the improperly withdrawn claims and withdraw finality of the Final Office Action. A copy of Applicant's Request is attached hereto as Exhibit F. On April 23, 2004, the Examiner mailed an Advisory Action denying Applicant's request. A copy of the Advisory Action is attached hereto as Exhibit G.

II. Arguments

Applicant submits that: (A) the Examiner's requirement to cancel elected claims in reply to the Final Office Action is improper; (B) Applicant is entitled to the rejoinder of claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276; and (C) the finality of the Final Office Action must be withdrawn. Each of these points are addressed below.

A. The Examiner's requirement for Applicant to cancel elected claims in reply to the Final Office Action is improper.

In the Final Office Action, the Examiner stated that "[a] complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01." (Final Office Action, page 2, fourth paragraph). Applicant submits that the Examiner's requirement to cancel elected claims that the Examiner has improperly characterized as non-elected claims in reply to the Final Office Action is improper because the Examiner's rationale set forth in the Final Office Action to require cancellation of the claims is not applicable.

The Examiner relies on MPEP § 821.01 to support the requirement to cancel claims. Applicant submits that MPEP § 821.01 is applicable in situations where an applicant has traversed the merits of a Restriction Requirement. (See, e.g., MPEP § 821.01, page 800-62, col.1 (August 2001)). A copy of MPEP § 821.01 is attached hereto as Exhibit H. In Applicant's reply to the Restriction Requirement, Applicant traversed the restriction requirement "to the extent that it fails to identify any linking claims." (Reply to Restriction Requirement, page 12, lines 3-4). Applicant did not traverse the designation of species made by the Examiner. Applicant traversed the procedural aspect of the Restriction Requirement (*i.e.*, failure to identify linking claims), not the merits of the Restriction Requirement. Accordingly, Applicant submits that MPEP § 821.01 is not applicable and that the withdrawn claims need not be cancelled in response to the Final Office Action.

B. The Examiner improperly withdrew claims in the Final Action.

Applicant submits that the Examiner improperly withdrew claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 in the Final Office Act on for at least one of the following grounds: (1) the Examiner had previously confirmed that the improperly withdrawn claims read on the elected species; (2) the improperly withdrawn claims include a feature that distinguishes the elected species from other species; and (3) the Examiner's rationale for withdrawing the claims is not applicable in view of the Restriction Requirement.

(1) The Examiner is on record as stating that the claims withdrawn read on the elected embodiment.

In the April Office Action, the Examiner stated that claims 131, 133, 135, 137-145, 205, 206, and 213-215 "read on the elected species as indicated by applicant in paper No. 6." (April Office Action, page 2, paragraph 1). Despite the Examiner's affirmance in the April Office Action that claims 131, 133, 135, 137-145, 205, 206, and 213-215 read on the elected species, the Examiner withdrew these claims on his own accord in the Final Office Action and is now requiring Applicant to cancel these claims in the next reply in order to be fully responsive to the Final Action. (See Final Office Action, page 2, paragraphs 2-4). Accordingly, Applicant submits that no fair opportunity is being provided to adequately traverse the Examiner's change in position with respect to Applicant's election submitted in reply to the Restriction Requirement.

(2) The improperly withdrawn claims include one of the features that distinguishes the elected species from other species.

The Examiner's Restriction Requirement separated the figures into six species. A copy of the original drawings is attached hereto as Exhibit I and is labeled according to each species set forth in the Restriction Requirement.

Species 1 and 2 are drawn to surface projections having included angles between the rear facet and the base of the surface projection of 90 degrees and less than 90 degrees, respectively. Species 4 is drawn to an embodiment that includes three types of surface projections not shown in species 1 to 3. Species 5 is drawn to an embodiment showing two of the surface projections of species 4 having a cleave

running therethrough. Species 6 is drawn to an embodiment of surface projections similar to those shown in Species 2, but having longitudinal and transverse cleaves running therethrough.

Applicant's elected embodiment, species 3, is drawn to surface projections having a facet with an included angle greater than 90 degrees. The included angle greater than 90 degrees is labeled in Fig. 13 in Exhibit I.

Applicant respectfully disagrees with the Examiner's contention that independent claim 131 is drawn to a non-elected species. The Examiner did not identify the subject matter of independent claim 131 as a patentably distinct species. Thus, Applicant should not be forced to cancel claims that cover subject matter which the Examiner has not indicated as being subject to restriction.

Further, as part of Applicant's reply to the April Office Action, Applicant amended independent claim 131 to recite that at least two surface projections each have a facet with "an included angle greater than 90 degrees." This feature distinguishes the species from other of the designated species, for example, species 1 and 2. Accordingly, Applicant submits that claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 read on species 3.

(3) The Examiner's rationale for withdrawing the improperly withdrawn claims is not applicable in view of the Restriction Requirement.

In the Final Rejection, the Examiner observed that Figs. 12-15 (species 3) had left and right facets that were identical instead of the left facet being steeper than the right facet. (Final Rejection, page 2, paragraph 3). Applicant submits that this observation is not relevant because at the time the Examiner made the restriction, all illustrated embodiments had a rearward portion with a slope steeper than the slope of a facet facing forward at least in part. Further, the configuration of the projection is the same in Figs. 12A and 12B except that the orientation of the projections of the implant surface is rotated 90° with respect to the rearward and forward portion of the implant. (Compare Figs. 12A and 12B). In particular, Figs. 12A and 12B are partial fragmentary views of an implant surface wherein the entire implant is not shown. Therefore, the reference points of the front, rear and sides of the implant are not illustrated in these

figures. Accordingly, the feature of the rearward portion having a steeper slope than the slope of a forward portion of the surface projection could not have been the basis of the Examiner's restriction. Thus, Applicant submits that the Examiner's rationale for withdrawing claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 is not applicable in view of the Restriction Requirement.

If the Examiner holds that the subject matter of Fig. 12B represents a patentably distinct species, it is respectfully requested that a further restriction be mailed to Applicant listing the subject matter of Fig. 12B as a patentably distinct species. In response to the further restriction, Applicant will cancel claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276 for subsequent filing in a divisional application.

C. The finality of the Final Office Action is improper.

The MPEP states that a rejection may properly be made final on a second action "except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)." (MPEP § 706.07(a), page 700-73, col. 1 (February 2003)). A copy of MPEP § 706.07(a) is attached hereto as Exhibit J. Applicant respectfully submits that the last office action was made final prematurely because a new ground of rejection was entered that was not necessitated by Applicant's amendment.

(1) The Examiner's new ground of rejection is completely unrelated to any prior rejections.

In the April Office Action, the Examiner rejected all claims under 35 U.S.C. § 112, second paragraph, because the difference between the phrase "bone engaging structures" and "surface projections" was not understood in the independent claims. (April Office Action, page 3, first paragraph). Applicant amended independent claims 1 and 219 to delete the phrase "bone engaging structures" and overcame the Examiner's rejection in Applicant's reply dated October 8, 2003.

In the Final Office Action, the Examiner rejected dependent claims 43 and 247 (dependent from claims 1 and 219, respectively) under 35 U.S.C. § 112, second

paragraph, because the Examiner did not understand the meaning and application of the phrase "motion preserving device" relative to a spinal implant. (Final Office Action, page 5, second paragraph). The issue of whether a spinal implant is a "motion preserving device" is an issue of first appearance in this case and is completely unrelated to any rejection made by the Examiner in the April Office Action. In particular, the rejection of claims 1 and 219 in the April Office Action addressed differences between "bone engaging structures" and "surface projections of the surface configuration." The rejection of claims 43 and 247 deal with the overall structure and function of the spinal implant itself and not to a specific surface configuration of the implant. Accordingly, the issues between the new ground of rejection and the previous rejection under 35 U.S.C. § 112, second paragraph, are separate and distinct issues from one another.

(2) Applicant's amendment of independent claims 1 and 219 did not affect the nature of claims 43 and 247.

Applicant's amendments to independent claims 1 and 219 did not further define the claims relative to a particular type or function of implant, which is the general focus of claims 43 and 247. Thus, the subject matter of claims 43 and 247 were unaffected by Applicant's amendments to claim 1 and 219. In particular, Applicant respectfully submits that deleting the phrase "bone engaging structure" from independent claims 1 and 219 did not necessitate the Examiner's new rejection of claims 43 and 247 regarding the phrase "motion preserving device."

III. Conclusion

In view of the above remarks, Applicant respectfully requests the Director to (1) rescind the Examiner's requirement that Applicant cancel elected claims, (2) rejoin claims 131, 133, 135, 137-145, 205, 206, 213-215, and 272-276, and (3) withdraw the finality of the Office Action dated January 7, 2004 pursuant to MPEP § 706.07(d) and issue a non-final action to provide Applicant the opportunity to fully address the Examiner's new ground of rejection.

This Petition is being filed from an action of an examiner in *ex parte* prosecution of an application which is not subject to appeal to the Board of Patent Appeals and Interferences or to the court (MPEP § 706.07(c)) pursuant to 37 C.F.R. § 1.181(a)(1). Further, this Petition is being filed within two months from the action complained of pursuant to 37 C.F.R. § 1.181(f), and does not require a fee.

To the extent any extension of time under 37 C.F.R. § 1.136 is required in connection with the filing of this Petition, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: June 22, 2004

By: _____
Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
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Exhibit A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,844	08/03/2001	Gary K. Michelson	IC1.0084-01000	8295

22882 7590 10/28/2002

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CHANTILLY, VA 201511101

EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY: tmm
ON: 10-30-02
ACTION REQUIRED: elect
DATE REQUIRED: 12-28-02

PTO-90C (Rev. 07-01)

tm 4-28-03

Office Action Summary	Application No.	Applicant(s)	
	09/921,844	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56,131-145 and 203-206* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56, 131-145, 203-206* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election of Species

I. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 - figure 4

Species 2 - figure 8

Species 3 - figure 12

Species 4 - figure 16

Species 5 - figure 19B

Species 6 - figure 20

Applicant is required under 35 U.S.C. 121 to elect a sing.e disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a reject on under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
October 24, 2002

BRUCE SNOW
PRIMARY EXAMINER

Exhibit B

PATENT
Attorney Docket No. 101.0084-01000
Customer No. 22882
Express Mail No. EV 044 233 658 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Gary K. Michelson, M.D.	
Serial No.: 09/921,844	Group Art Unit: 3738
Filed: August 3, 2001	Examiner: B. Snow
For: SPINAL IMPLANT SURFACE CONFIGURATION	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

REPLY TO RESTRICTION REQUIREMENT

In reply to the restriction requirement dated October 28, 2002, Applicant provisionally elects to prosecute claims 1, 3, 5-15, 17-51, 131, 133, 135-145, and 203-206 drawn to Species 3, Figs. 12-15. In addition, the following amendments and remarks are submitted:

IN THE CLAIMS:

Please amend claims 1, 7-11, 18-20, 32, 50, 131, and 143 (with the changes as shown in the attachment) to read as follows:

--1. (Amended) An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end for introduction of said spinal implant into the spine, an opposite trailing end, and spaced apart sides therebetween;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement in

engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of bone engaging structures formed on said upper and lower surfaces, each of said bone engaging structures having a base, at least two of said bone engaging structures each comprising at least one surface projection having at least one forward facing facet directed at least in part toward said leading end and at least one rearward facet directed at least in part toward said trailing end, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said surface projection having opposed side facets extending from said base and being directed generally toward said spaced apart sides of said implant, respectively, said side facets located between said forward facet and said rearward facet of said surface projection, said side facets converging toward each other in a direction away from said base, said side facets having a maximum width therebetween at said base, said base being spaced apart from a base of another of said bone engaging structures by a distance no greater than one-half the maximum width of said surface projection, said forward facets of said at least two of said bone engaging structures facing the same direction.

7. (Amended) The spinal implant of claim 6, wherein said opposed side facets converge to form a peak at the top of said surface projection.

8. (Amended) The spinal implant of claim 7, wherein said peaks of at least two of said surface projections are aligned along lines that are at least one of perpendicular, parallel, and diagonal to the longitudinal axis of said implant.

9. (Amended) The spinal implant of claim 1, wherein one of said opposed side facets of said surface projection includes a left forward side facet and the other of said opposed side facets includes a right forward side facet directed toward said leading end and said sides, respectively, of said implant.

10. (Amended) The spinal implant of claim 1, wherein one of said opposed side facets of said surface projection includes a left rearward side facet and the other of said opposed side facets includes a right rearward side facet directed toward said trailing end and sides, respectively, of said implant.

11. (Amended) The spinal implant of claim 9, wherein one of said opposed side facets of said surface projection includes a left rearward side facet and the other of said opposed side facets includes a right rearward side facet directed toward said trailing end and sides, respectively, of said implant.

18. (Amended) The spinal implant of claim 13, wherein at least one of said grooves has a horizontal cross-sectional shape that is one of a v-shape, u-shape, and a box-like shape.

19. (Amended) The spinal implant of claim 1, wherein said bone engaging structures are oriented relative to one another to form an array.

20. (Amended) The spinal implant of claim 1, wherein said bone engaging structures are geometrically disposed relative to one another.

32. (Amended) The spinal implant of claim 31, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

50. (Amended) The spinal implant of claim 49, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

131. (Amended) An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end, an opposite trailing end, and spaced apart opposite sides therebetween;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart opposite sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of bone engaging structures formed on said upper and lower surfaces, at least two of said bone engaging structures each comprising at least one surface projection having at least one forward facing facet directed at least in part toward said one of said spaced apart opposite sides and at least one rearward facet directed at least in part toward the other one of said spaced apart opposite sides, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said

rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said at least one surface projection having opposed side facets directed generally toward said leading and trailing ends, respectively, said side facets located between said forward facet and said rearward facet of said surface projection, said side facets converging toward each other in a direction away from the base of said projection, said forward facets of said at least two of said bone engaging structures facing the same direction.

143. (Amended) The spinal implant of claim 142, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.--.

Please add the following new claims:

--207. The spinal implant of claim 1, wherein said bases of at least two of said bone engaging structures are adjacent one another.

208. The spinal implant of claim 1, wherein said implant has a longitudinal axis and said bases of at least two adjacent bone engaging structures are spaced apart from one another along a direction generally parallel to the longitudinal axis of said implant.

209. The spinal implant of claim 1, wherein said implant has a longitudinal axis and said bases of at least two adjacent bone engaging structures are spaced apart from one another along a direction generally transverse to the longitudinal axis of said implant.

210. The spinal implant of claim 1, in combination with a device for forming said bone

engaging structures on said upper and lower surfaces of said implant.

211. The combination of claim 210, wherein said device is a milling instrument.

212. The combination of claim 210, wherein said device includes a cutting tool with a V-shaped profile.

213. The spinal implant of claim 131, wherein the bases of at least two of said bone engaging structures are adjacent one another.

214. The spinal implant of claim 131, wherein said implant has a longitudinal axis and the bases of at least two adjacent bone engaging structures are spaced apart from one another along a direction generally parallel to the longitudinal axis of said implant.

215. The spinal implant of claim 131, wherein said implant has a longitudinal axis and the bases of at least two adjacent bone engaging structures are spaced apart from one another along a direction generally transverse to the longitudinal axis of said implant.

216. The spinal implant of claim 131, in combination with a device for forming said bone engaging structures on said upper and lower surfaces of said implant.

217. The combination of claim 216, wherein said device is a milling instrument.

218. The combination of claim 216, wherein said device includes a cutting tool with a V-shaped profile.

219. An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end for introduction of said spinal implant into the spine, an opposite trailing end, and spaced apart sides therebetween;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of bone engaging structures formed on said upper and lower surfaces, at least one of said bone engaging structures comprising surface projections having at least one forward facing facet directed at least in part toward said leading end and at least one rearward facet directed at least in part toward said trailing end, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said surface projections having opposed side facets directed generally toward said sides of said implant, said side facets located between said forward facet and said rearward facet of said surface projections, said side facets converging toward each other in a direction away from the base of said projections, said rearward facet having an included angle between said rearward facet and the base greater than 90 degrees relative to at least one of said upper and lower surfaces of said implant.

220. The spinal implant of claim 219, wherein said opposed side facets converge to form a peak at the top of each of said surface projections.

221. The spinal implant of claim 220, wherein said peaks are aligned along lines that are at least one of perpendicular, parallel, and diagonal to the longitudinal axis of said implant.

222. The spinal implant of claim 219, wherein adjacent side facets of adjacent surface projections are spaced apart to define a groove therebetween.

223. The spinal implant of claim 222, wherein a plurality of adjacent surface projections are spaced apart to form a plurality of grooves therebetween.

224. The spinal implant of claim 223, wherein at least one of said grooves is parallel to the longitudinal axis of said implant.

225. The spinal implant of claim 223, wherein at least one of said grooves is at an angle to the longitudinal axis of said implant.

226. The spinal implant of claim 223, wherein at least two of said grooves cross each other.

227. The spinal implant of claim 223, wherein at least one of said grooves has a horizontal cross-sectional shape that is one of a v-shape, u-shape, and a box-like shape.

228. The spinal implant of claim 219, wherein said upper and lower surfaces of said implant are at least in part arcuate.

229. The spinal implant of claim 219, wherein at least one of said leading end, trailing end, and sides are curved.

230. The spinal implant of claim 219, wherein said sides are curved.

231. The spinal implant of claim 219, wherein each of said leading end, trailing end, and sides are curved.

232. The spinal implant of claim 231, wherein said leading end, trailing end, and sides form a circle.

233. The spinal implant of claim 219, wherein said upper and lower surfaces of said implant are at least in part planar.

234. The spinal implant of claim 219, wherein said upper and lower surfaces converge along the length of said implant.

235. The spinal implant of claim 219, wherein said implant comprises a material other than bone.

236. The spinal implant of claim 219, wherein said implant comprises bone.

237. The spinal implant of claim 236, wherein said bone includes cortical bone.

238. The spinal implant of claim 219, wherein said implant comprises bone growth promoting material.

239. The spinal implant of claim 238, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

240. The spinal implant of claim 219, wherein said implant is treated with a bone growth promoting substance.

241. The spinal implant of claim 219, wherein said implant is a source of osteogenesis.

242. The spinal implant of claim 219, wherein said implant is at least in part bioabsorbable.

243. The spinal implant of claim 219, wherein said implant comprises metal.

244. The spinal implant of claim 243, wherein said metal includes titanium.

245. The spinal implant of claim 219, wherein said implant comprises at least one of a plastic material and a ceramic material.

246. The spinal implant of claim 219, wherein said implant is formed of a porous material and a material that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

247. The spinal implant of claim 219, wherein said implant is a motion preserving device adapted to space apart and allow motion between the adjacent vertebral bodies.

248. The spinal implant of claim 219, wherein said spinal implant is a fusion implant.

249. The spinal implant of claim 248, wherein said upper and lower surfaces include at least one opening to permit bone growth from one of the adjacent vertebral bodies to the other one of the adjacent vertebral bodies through said implant.

250. The spinal implant of claim 248, wherein said implant has an internal chamber and an access opening for accessing said internal chamber.

251. The spinal implant of claim 250, wherein said upper and lower surfaces include at least one opening in communication with said internal chamber to permit bone growth from one of the adjacent vertebral bodies to the other one of the adjacent vertebral bodies through said implant.

252. The spinal implant of claim 250, wherein said internal chamber is capable of containing bone growth promoting material.

253. The spinal implant of claim 252, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

254. The spinal implant of claim 219, further comprising at least one opening capable of retaining fusion promoting materials.

255. The spinal implant of claim 219, wherein the bases of at least two of said bone engaging structures are adjacent one another.

256. The spinal implant of claim 219, in combination with a device for forming said bone engaging structures on said upper and lower surfaces of said implant.

257. The combination of claim 256, wherein said device is a milling instrument.

258. The combination of claim 256, wherein said device includes a cutting tool with a V-shaped profile.—.

REMARKS

Applicant amended claims 1, 7-11, 18-20, 32, 50, 131, and 143, and added new claims 207-258 to further define Applicant's invention. Support for dependent claims 207-209, 213-215, and 255 is found at least in the specification on page 4, lines 20 and 21, claim 12 as originally filed, and Figs. 12 and 15. Support for dependent claims 210-212, 216-218, and 256-258 is found at least on page 5, line 22 to page 6, line 4 of the specification. Support for new independent claim 219 is found at least in claims 1, 3, and 5 as originally filed. Support for new claims 220-254 is found at least in the original dependent claims directed to corresponding subject matter that depend from independent claim 1 in the original claims as filed. New claims 207-258 read on elected

species 3 of the Restriction Requirement. Applicant submits that claims 1, 3, 5-15, 17-51, 131, 133, 135-145, and 203-206 read on elected species 3.[1]

Applicant traverses the restriction requirement to the extent that it fails to identify any linking claims. Currently, elected independent claim 1 is a linking claim to at least species 1-4 and 6. Applicant submits that upon allowance of linking claim 1, at least the following non-elected dependent claims (with exemplary species in parenthesis) must be rejoined and examined under 37 C.F.R. § 1.104 for patentability: claim 2 (species 1); claim 4 (species 2 and 6); claim 16 (species 4); and claims 52-56 (species 6).

Elected independent claim 131 is a linking claim to at least species 1-3 and 6. Applicant submits that upon allowance of linking claim 131, at least the following non-elected dependent claims (with exemplary species in parenthesis) must be rejoined and examined under 37 C.F.R. § 1.104 for patentability: claim 132 (species 1); and claim 134 (species 2 and 6).

Applicant respectfully requests the Examiner acknowledge that independent claims 1 and 131 are linking claims and include form paragraph 8.12 in the next Office Action as is required by MPEP § 809.03. (See the "Examiner note" to form paragraph 8.12 which states that the paragraph "must be included in any restriction requirement with at least one linking claim present; MPEP § 809.03, page 800-52 1st col. (August 2001)). Applicant respectfully reminds the Examiner that according to MPEP § 809, "should any linking claim be allowed, the restriction requirement must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from

1 Claims 28-42, 50, 142, 143, and 203-206 include a recitation of a material or composition. (See, MPEP § 601.01(f), page 600-14, col. 2 (August 2001)). Claims 9-11, 21, 25, 43, 47, 139, and 144 recite subject matter that does not necessitate illustration. (See, 35 U.S.C. § 113, first sentence).

consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability." (See, MPEP § 809, page 800-48, 2nd col., and MPEP §§ 809.03 and 809.04, page 800-52 (August 2001)).

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this response, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: 1-28-03

By _____
Amedeo F. Ferraro
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PATENT
Attorney Docket No. 101.0084-01000
Customer No. 22882
Express Mail No. EV 044 233 658 US

CHANGES TO THE CLAIMS

1. An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end for introduction of said spinal implant into the spine, an opposite trailing end, and spaced apart sides therebetween;

opposite upper and lower surfaces between said eading and trailing ends and said spaced apart sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of bone engaging structures formed on said upper and lower surfaces, each of said bone engaging structures having a base, at least two of said bone engaging structures each comprising at least one surface projections having at least one forward facing facet directed at least in part toward said leading end and at least one rearward facet directed at least in part toward said trailing end, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said surface projections having opposed side facets extending from said base and being directed generally toward said spaced apart sides of said implant, respectively, said side facets located between said forward

facet and said rearward facet of said surface projections, said side facets converging toward each other in a direction away from saidthe base, said side facets having a maximum width therebetween at said base, said base being spaced apart from a base of another of said bone engaging structures by a distance no greater than one-half the maximum width of said surface projection, said forward facets of said at least two of said bone engaging structures facing the same direction ~~of said projections~~.

7. The spinal implant of claim 6, wherein said opposed side facets converge to form a peak at the top of ~~each of~~ said surface projections.

8. The spinal implant of claim 7, wherein said peaks of at least two of said surface projections are aligned along lines that are at least one of perpendicular, parallel, and diagonal to the longitudinal axis of said implant.

9. The spinal implant of claim 1, wherein one of said opposed side facets~~each~~ of said surface projections includes a left forward side facet and the other of said opposed side facets includes a right forward side facet directed toward said leading end and said sides, respectively, of said implant.

10. The spinal implant of claim 1, wherein one of said opposed side facets~~each~~ of said surface projections includes a left rearward side facet and the other of said opposed side facets includes a right rearward side facet directed toward said trailing end and sides, respectively, of said implant.

11. The spinal implant of claim 9, wherein one of said opposed side facets~~each~~ of said surface projections includes a left rearward side facet and the other of said

opposed side facets includes a right rearward side facet directed toward said trailing end and sides, respectively, of said implant.

18. The spinal implant of claim 13, wherein at least one of said grooves has a horizontal cross-sectional shape ~~selected from~~ that is one of a v-shape, u-shape, and a box-like shape.

19. The spinal implant of claim 1, wherein said bone engaging structures~~projections~~ are oriented relative to one another to form an array.

20. The spinal implant of claim 1, wherein said bone engaging structures~~projections~~ are geometrically disposed relative to one another.

32. The spinal implant of claim 31, wherein said bone growth promoting material is ~~selected from~~ one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

50. The spinal implant of claim 49, wherein said bone growth promoting material is ~~selected from~~ one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

131. An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end, an opposite trailing end, and spaced apart opposite sides therebetween;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart opposite sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other

of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of bone engaging structures formed on said upper and lower surfaces, at least ~~one~~ two of said bone engaging structures each comprising at least one surface projections having at least one forward facing facet directed at least in part toward said one of said spaced apart opposite sides and at least one rearward facet directed at least in part toward the other one of said spaced apart opposite sides, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said at least one surface projections having opposed side facets directed generally toward said leading and trailing ends, respectively, said side facets located between said forward facet and said rearward facet of said surface projections, said side facets converging toward each other in a direction away from the base of said projections, said forward facets of said at least two of said bone engaging structures facing the same direction.

143. The spinal implant of claim 142, wherein said bone growth promoting material is ~~selected from~~ one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

Exhibit C

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,844	08/03/2001	Gary K. Michelson	101.0084-01000	8295

22882 7590 04/23/2003

MARTIN & FERRARO
14500 AVION PARKWAY
SUITE 300
CHANTILLY, VA 201511101

EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY: YMM
ON: 7-28-03
ACTION REQUIRED: RESP
DATE REQUIRED: 7-23-03

PTO-90C (Rev. 07-01)

L/E 10-23-03

Office Action Summary	Application No.	Applicant(s)	
	09/921,844	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56,131-145 and 203-258* is/are pending in the application.

4a) Of the above claim(s) *2,4,16,52-56,132 and 134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-15,17-51,131,133,135-145 and 203-258* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 8*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Claims 1, 3, 5-15, 17-51, 131, 133, 135-145, 203-258 read on the elected species as indicated by applicant in paper No. 6. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Applicant's election with traverse of Species 3 (figure 12) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that "*Applicant traverses the restriction requirement to the extent that it fails to identify any linking claim*". This is not found persuasive. Applicant's argument does not address the basis of a species restriction. A species restriction states that the Examiner believes there are patentable distinct embodiments; applicant can agree or disagree. Applicant's response stating that the restriction requirement fails to identify any linking claim is not an appropriate argument. When regarding a species restriction a discussion regarding generic claims is more likely reasonable.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

All claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 131, and 219, what is the difference between "bone engaging structures" and "surface projections"? Please direct to specification and drawings for all support.

Claim 131 is ambiguous. The claim reads, "*surface projection having opposed side facets directed generally toward said leading and trailing ends, respectively, said side facets located between said forward facet and said rearward facet*". The side facets are directed towards the leading and trailing ends and so are the forward and rearward facets? Additionally, this claim is in direct conflict with claim 1 and 219. This claim is confusing the issue.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, all claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Due to the large number of claims only some specific claims will be addressed as examples purposes only. ***It is Applicant's responsibility to ensure all claimed limitations are shown in the drawings or to remove limitations or cancel the claims of the limitations not shown.***

Examples of claims not shown: Claim 6, the bases are spaced apart; Claim 8, the peaks are aligned along lines that are perpendicular to the longitudinal axis; Claims 9-13; Claim 15; Claim 18; Claim 21, Claim 131, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-15, 17-51, 131, 133, 135-145, 203-258 (all claims not withdrawn from consideration) rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al (6,482,233).

Aebi et al teaches a spinal implant comprising bone engaging structures that are generally pyramid-shaped formed on the upper and lower surfaces of the implant. The engaging structures are slanted towards the anterior therefore having a forward (anterior) facing facet that is shorter than a rearward facing facet and said forward facing facet has a steeper slope; the structures further include side facets. Applicant claims the opposite Aebi et al claiming the bone engaging structures slant rearward

(posteriorly). However, both Aebi et al and applicant teach the bone engaging structures slant in a direction such to allow ease of insertion and to avoid retropulsion. See Abei et al column 4, lines 30-34 and applicant's specification page 5, lines 5-9 and lines 15-19. It would have been obvious to one having ordinary skill in the art to have slanted the bone engaging structures of Aebi et al posteriorly such that the implant could be introduced posterior-laterally and/or resist movement in the direction towards the spinal cord when a surgeon deems it necessary. Note that Aebi et al teaches the steeper angled face can be "from about 0 to 30 degrees" which the Examiner interprets to include negative angles.

In the alternative, under 35 U.S.C. 103(a): Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, range, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Claims 1, 3, 5-15, 17-51, 131, 133, 135-145, 203-258 (all claims not withdrawn) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brantigan (4,834,757).

Brantigan teaches a spinal implant comprising bone engaging structures which are slanted towards the trailing end comprising a forward (anterior) facing facet that is

longer than a rearward facing facet and said rearward facing facet has a steeper slope; the structures further include side facets. Brantigan teaches the structures are spaced apart forming grooves which are "u-shaded" or "box like-shaped".

In the alternative, under 35 U.S.C. 103(a): Many of applicant's dependent claims claim a wide range of possibilities, for example, an angle can be less than 90 degrees, perpendicular, or greater than 90 degrees; the groove can be v-shaped, u-shaped, box-like shape; etc, lacking any criticality in the specification, the use of any claimed variation, ranges, or configuration in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art.

Additionally, many of the dependent claims claim elements/materials/shapes/tools/etc. which are taught by the reference or are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
April 16, 2003

BRUCE SNOW
PRIMARY EXAMINER

Notice of References Cited	Application/Control No. 09/921,844	Applicant(s)/Patent Under Reexamination MICHELSON, GARY K.	
	Examiner Bruce E Snow	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6482233	11-2002	Aebi et al	623/17.11
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

OMB 0651-0031

Express Mail No. EV 044 233 658 US

for FORM PTO-1449	Attorney Docket Number 101.0084-01000	Customer No. 22882	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant Gary K. Michelson, M.D.	Application Number 09/921,844	
(Use several sheets if necessary) Sheet 1 of 1	Filing Date August 3, 2001	Group Art Unit 3738	Examiner B. Snow

JAN 2 8 2003 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	4,531,244	7/1985	Hamas			
	2	4,673,409	6/1987	Van Kampen			
	3	4,795,742	1/1989	Crowinshield et al.			
	4	4,865,603	9/1989	Noiles			
	5	4,944,763	7/1990	Willert et al.			
	6	4,955,907	9/1990	Ledergerber			
	7	5,553,476	9/1996	Oehy et al.			
	8	5,716,412	2/1998	DeCarlo Jr. et al.			
	9	5,755,799	5/1998	Oehy et al.			
	10	5,899,941	5/1999	Nishijima et al.			
	11	6,174,334	1/2001	Suddaby			
	12	6,190,414	2/2001	Young et al.			
	13	6,258,125	7/2001	Paul et al.			

RECEIVED
JAN 31 2003
TECHNOLOGY CENTER R3700

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	14	WO 98/58604	12/1998	WIPO			N/A

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER [signature] DATE CONSIDERED 4/16/05

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Form PTO-1449 MASTER

Customer No. 22882
Express Mail No.: EL849519495US

PTO-1449	Docket Number (Optional) 101.0084-01000	Application Number (Div. of 09/457,228
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant: Gary K. Michelson, M.D.	
(Use several sheets if necessary) Sheet 1 of 1	Filing Date: August 3, 2001	Group Art Unit: (3728)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,349,921	09/1982	Kuntz			
	4,834,757	05/1989	Brantigan			
	5,522,899	06/1996	Michelson			
	5,593,409	01/1997	Michelson			
	5,609,635	03/1997	Michelson			
	5,683,464	11/1997	Wagner et al.			
	5,860,973	01/1999	Michelson			

JC973 U.S. PTO 09/92184 08/03/01

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION (YES/NO)

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER: DATE CONSIDERED 4/16/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Exhibit D

PATENT
Attorney Docket No. 101.0084-01000
Customer No. 22882
Express Mail Label No. ET371606145US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Gary K. Michelson	)	
	)	
Serial No.: 09/921,844	)	Group Art Unit: 3738
	)	
Filed: August 3, 2001	)	Examiner: B. Snow
	)	
For: SPINAL IMPLANT SURFACE CONFIGURATION	)	Confirmation No. 8295
	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

AMENDMENT

In reply to the Office Action dated April 23, 2003, the period for reply having been extended for three (3) months by a request for extension and fee payment filed concurrently herewith, please amend the application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 6 of this paper.

Amendments to the Drawings begin on page 20 of this paper.

Remarks begin on page 21 of this paper.

An **Appendix** including a courtesy copy of 9 drawing replacement sheets is attached following page 25 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please add the following new paragraphs after the first full paragraph on page 7 of the specification:

--FIG. 1A is a perspective view of an implant having arcuate surfaces and an end cap in accordance with an embodiment of the present invention.

FIG. 1B is a top elevational view of an implant having a leading end, a trailing end, and sides forming a circle in accordance with an embodiment of the present invention.

FIG. 1C is a graphical representation of a motion preserving device in accordance with an embodiment of the present invention. --

Please replace the twelfth full paragraph on page 7 of the specification with the paragraph below:

FIG. 12A~~12~~ is an enlarged fragmentary top plan view of a third embodiment of the implant surface of the present invention from a view taken along area 12 of FIG. 1.

Please add the following new paragraph after the twelfth full paragraph on page 7 of the specification:

--FIG. 12B is an enlarged fragmentary top plan view of another embodiment of the implant surface of the present invention from a view taken along area 12 of FIG. 1.--

Please replace the first full paragraph on page 8 of the specification with the paragraph below:

FIG. 13 is a fragmentary side elevation view of the implant surface of FIG. 12A~~12~~ from a view taken along area 13 of FIG. 2.

Please replace the second full paragraph on page 8 of the specification with the paragraph below:

FIG. 14 is a fragmentary end view of FIG. 12A~~12~~.

Please add the following new paragraphs after the second full paragraph on page 8 of the specification:

--FIG. 14A is an enlarged fragmentary side view of a groove having a U-shape in accordance with an embodiment of the present invention from a view taken along area 14A of FIG. 14.

FIG. 14B is an enlarged fragmentary side view of a groove having a box-shape in accordance with an embodiment of the present invention from a view taken along area 14B of FIG. 14.

FIG. 14C is a fragmentary end view of a plurality of surface projections spaced apart from one another in accordance with an embodiment of the present invention.--

Please replace the third full paragraph on page 8 of the specification with the paragraph below:

FIG. 15 is a fragmentary perspective view of the implant surface of FIG. 12A~~12~~.

Please replace the paragraph bridging pages 10 and 11 of the specification with the paragraph below:

In this embodiment of surface configuration 120, a plurality of surface projections 122 are spaced apart laterally (side to side) by longitudinal grooves 130 formed along the longitudinal axis L of implant 100. In one embodiment, longitudinal grooves 130 have a V-shaped horizontal cross-section. The lower most portions of left and right side facets 132, 134 of consecutive side-by-side projections 122 can be coincident with each other or may be spaced apart, any space therebetween can be at least in part flat, curved, sloped or otherwise

configured. Each surface projection 122 has left and right side facets 132, 134 that converge to form a high point or peak 136 at the top of each surface projection 122. Each peak 136 can be aligned along lines that are perpendicular, parallel, and/or diagonally oriented to longitudinal axis L of implant 100. The left and right side facets 132,134 resist side-to-side motion of implant 100 after it is inserted into the implantation space. Peaks 136 engage the bone of vertebral bodies V adjacent to implant 100 in the implantation site. It is appreciated that in a variation of the present invention, the peaks may be modified such as to be truncated or cut off to have a broader rather than sharper~~shaper~~ upper most surface. Moreover, the peaks can be cleaved in one or more directions so as to increase the surface area useful for engaging the bone of the vertebral bodies. The relieved areas of the cleaved projections are useful for containing and carrying fusion promoting substances other than bone such as bone morphogenetic proteins and genetic materials coding for the production of bone, or bone itself which could by way of example be in the form of a paste. It is further appreciated that for all the various embodiments of the surface configuration of the present invention, longitudinal grooves 130 can have horizontal cross-sections in a variety of configurations such as, without limitation, square-shaped or U-shaped configurations.

Please replace the paragraph bridging pages 19 and 20 of the specification with the paragraph below:

The spinal implants of the present invention can be for the purpose of achieving fusion. The upper and lower surfaces of the fusion implants can include at least one opening, each in communication with the other, to permit for the growth of bone from vertebral body to adjacent vertebral body through the implant. The implant can have an internal chamber and may also have an access opening for accessing the internal chamber, in which case the implant can further have a cover such as a cap 101' (shown in Fig. 1A) to close the access opening at least in part. Openings in the upper and lower surfaces of the

implant can communicate with the internal chamber to permit further growth of bone from vertebral body to adjacent vertebral body through the implant. The internal chamber can contain bone growth promoting materials, including but not limited to, bone, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone. The implants of the present invention can be formed of a material that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end for introduction of said spinal implant into the spine, an opposite trailing end, ~~and~~ spaced apart sides therebetween, and a mid-longitudinal axis passing through said leading and trailing ends;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of surface projections~~bone engaging structures~~ formed on said upper and lower surfaces of said implant, ~~each of said bone engaging structures having a base, at least two of said bone engaging structures each comprising~~ at least a first and a second of said~~one~~ surface projections each~~projection~~ having at least one forward facing facet directed at least in part toward said leading end and at least one rearward facet directed at least in part toward said trailing end, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, at least a portion of said rearward facet of said first surface projection overlying a portion of said forward facet of said second surface projection ~~said surface projection having opposed side facets extending from said base and being directed generally toward said spaced apart sides of said implant, respectively, said side facets located between said forward facet and said rearward facet of said surface projection, said side facets converging toward each other in a~~

~~direction away from said base, said side facets having a maximum width therebetween at said base, said base being spaced apart from a base of another of said bone engaging structures by a distance no greater than one half the maximum width of said surface projection, said forward facets of said at least two of said bone engaging structures facing the same direction.~~

Claim 2 (cancelled).

3. (original) The spinal implant of claim 1, wherein said rearward facet is at an angle to at least one of said upper and lower surfaces of said implant.

Claim 4 (cancelled).

5. (original) The spinal implant of claim 3, wherein said angle is greater than 90 degrees.

Claims 6-18 (cancelled).

19. (currently amended) The spinal implant of claim 1, wherein said surface projections~~bone engaging structures~~ are oriented relative to one another to form an array.

20. (currently amended) The spinal implant of claim 1, wherein said surface projections~~bone engaging structures~~ are geometrically disposed relative to one another.

21. (original) The spinal implant of claim 1, wherein said upper and lower surfaces of said implant are at least in part arcuate.

22. (original) The spinal implant of claim 1, wherein at least one of said leading end, trailing end, and sides are curved.

23. (original) The spinal implant of claim 1, wherein said sides are curved.

24. (original) The spinal implant of claim 1, wherein each of said leading end, trailing end, and sides are curved.

25. (original) The spinal implant of claim 24, wherein said leading end, trailing end, and sides form a circle.

26. (original) The spinal implant of claim 1, wherein said upper and lower surfaces of said implant are at least in part planar.

27. (currently amended) The spinal implant of claim 1, wherein said upper and lower surfaces converge toward each other along at least a portion of the length of said implant.

28. (original) The spinal implant of claim 1, wherein said implant comprises a material other than bone.

29. (original) The spinal implant of claim 1, wherein said implant comprises bone.

30. (original) The spinal implant of claim 29, wherein said bone includes cortical bone.

31. (original) The spinal implant of claim 1, wherein said implant comprises bone growth promoting material.

32. (previously presented) The spinal implant of claim 31, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

33. (original) The spinal implant of claim 1, wherein said implant is treated with a bone growth promoting substance.

34. (original) The spinal implant of claim 1, wherein said implant is a source of osteogenesis.

35. (original) The spinal implant of claim 1, wherein said implant is at least in part bioabsorbable.

36. (original) The spinal implant of claim 1, wherein said implant comprises metal.

37. (original) The spinal implant of claim 36, wherein said metal is ASTM material suitable for use as a spinal fusion implant.

38. (original) The implant of claim 36, wherein said metal includes titanium.

39. (original) The implant of claim 1, wherein said implant comprises a plastic material.

40. (original) The implant of claim 1, wherein said implant comprises a ceramic material.

41. (original) The implant of claim 1, wherein said implant is formed of a porous material.

42. (original) The implant of claim 1, wherein said implant is formed of a material that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

43. (original) The spinal implant of claim 1, wherein said implant is a motion preserving device adapted to space apart and allow motion between the adjacent vertebral bodies.

44. (original) The spinal implant of claim 1, wherein said spinal implant is a fusion implant.

45. (currently amended) The spinal implant of claim 44, wherein said upper and lower surfaces include at least one opening to permit bone growth from ~~one of the~~ adjacent vertebral bodybodies to ~~the other one of the~~ adjacent vertebral bodybodies through said implant.

46. (original) The spinal implant of claim 44, wherein said implant has an internal chamber and an access opening for accessing said internal chamber.

47. (original) The spinal implant of claim 46, wherein said implant has a cap for closing said access opening.

48. (currently amended) The spinal implant of claim 46, wherein said upper and lower surfaces include at least one opening in communication with said internal chamber to permit bone growth from ~~one of the~~ adjacent vertebral bodybodies to ~~the other one of the~~ adjacent vertebral bodybodies through said implant.

49. (original) The spinal implant of claim 46, wherein said internal chamber is capable of containing bone growth promoting material.

50. (previously presented) The spinal implant of claim 49, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

51. (original) The spinal implant of claim 1, further comprising at least one opening capable of retaining fusion promoting materials.

52. (withdrawn) The spinal implant of claim 1, further comprising at least one cut cleaving said surface projection into at least two portions.

53. (withdrawn) The spinal implant of claim 52, further comprising at least a second cut cleaving said surface projection into at least four portions.

54. (withdrawn) The spinal implant of claim 52, where said cut penetrates said surface projection at a depth substantially equal to that of the height of said surface projection.

55. (withdrawn) The spinal implant of claim 53, where said second cut penetrates said surface projection at a depth substantially equal to that of the height of said surface projection.

56. (withdrawn) The spinal implant of claim 52, wherein said cut is oriented along one of the mid-longitudinal~~ongitudinal~~ axis of said implant, an axis perpendicular to the mid-longitudinal~~ongitudinal~~ axis of said implant, and an axis at an angle between the mid-longitudinal~~ongitudinal~~ axis and the axis perpendicular to the mid-longitudinal~~ongitudinal~~ axis of said implant.

Claims 57-130 (cancelled).

131. (currently amended) An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end, an opposite trailing end~~, and spaced apart opposite sides therebetween~~, a mid-longitudinal axis passing through said leading and trailing ends, and right and left sides between said leading and trailing ends, said right and left sides being spaced apart on opposite sides of the mid-longitudinal axis and;

opposite upper and lower surfaces between said leading and trailing ends and said ~~spaced apart opposite~~ right and left sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of surface projections~~bone engaging structures~~ formed on said upper and lower surfaces of said implant, each of said surface projections having a plurality of facets, each of said facets having a perimeter defining each facet, ~~at least two of said bone engaging structures each comprising~~ at least a first and a second of said~~one~~

surface projections eachprojection having at least one rightforward-facing facet directed at least in part toward said right sideone-of-said-spaced-apart-opposite-sides and at least one rearwardleft facet directed at least in part toward said left sidethe-other-one-of-said-spaced-apart-opposite-sides, each of said right and left facetsforward-facet-and-rearward-facet having a length and a slope, the length of said forwardright facet being longer than the length of said rearwardleft facet, the slope of said rearwardleft facet being steeper than the slope of said forwardright facet, said first and second surface projections having at least one facet with the perimeter of said at least one facet having at least a first and a second portion arranged to form an included angle greater than 90 degrees between said first and second portions of the perimeter-said-at-least-one-surface-projection-having-opposed-side-facets-directed-generally-toward-said-leading-and-trailing-ends,-respectively,-said-side-facets-located-between-said-forward-facet-and-said-rearward-facet-of-said-surface-projection,-said-side-facets-converging-toward-each-other-in-a-direction-away-from-the-base-of-said-projection,-said-forward-facets-of-said-at-least-two-of-said-bone-engaging-structures-facing-the-same-direction.

Claim 132 (cancelled).

133. (currently amended) The spinal implant of claim 131, wherein said rearwardleft facet is at an angle to at least one of said upper and lower surfaces of said implant.

Claim 134 (cancelled).

135. (original) The spinal implant of claim 133, wherein said angle is greater than 90 degrees.

Claim 136 (cancelled).

137. (currently amended) The spinal implant of claim 131~~124~~, wherein said projections are oriented relative to one another to form an array.

138. (original) The spinal implant of claim 131, wherein said projections are geometrically disposed relative to one another.

139. (original) The spinal implant of claim 131, wherein said upper and lower surfaces of said implant are at least in part arcuate.

140. (original) The spinal implant of claim 131, wherein said upper and lower surfaces of said implant are at least in part planar.

141. (currently amended) The spinal implant of claim 131, wherein said upper and lower surfaces converge toward each other along at least a portion of the length of said implant.

142. (original) The spinal implant of claim 131, wherein said implant comprises bone growth promoting material.

143. (previously presented) The spinal implant of claim 142, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

144. (original) The spinal implant of claim 131, wherein said implant is a motion preserving device adapted to space apart and allow motion between the adjacent vertebral bodies.

145. (original) The spinal implant of claim 131, wherein said spinal implant is a fusion implant.

Claims 146-202 (cancelled).

203. (previously presented) The spinal implant of claim 1, in combination with a fusion promoting substance.

204. (previously presented) The spinal implant of claim 203, wherein said fusion promoting substance includes at least one of bone, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

205. (previously presented) The spinal implant of claim 131, in combination with a fusion promoting substance.

206. (previously presented) The spinal implant of claim 205, wherein said fusion promoting substance includes at least one of bone, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

207. (currently amended) The spinal implant of claim 1, wherein each of said first and second surface projections have a base that is~~said bases of at least two of said bone engaging structures are~~ adjacent to one another.

208. (currently amended) The spinal implant of claim 1, wherein each of said first and second surface projections have a base, said bases being~~said implant has a longitudinal axis and said bases of at least two adjacent bone engaging structures are~~

spaced apart from one another along a direction generally parallel to the mid-longitudinal~~ongitudinal~~ axis of said implant.

209. (currently amended) The spinal implant of claim 1, wherein each of said first and second surface projections have a base, said bases being~~said implant has a longitudinal axis and said bases of at least two adjacent bone engaging structures are~~ spaced apart from one another along a direction generally transverse to the mid-longitudinal~~ongitudinal~~ axis of said implant.

Claims 210-212 (cancelled).

213. (currently amended) The spinal implant of claim 131, wherein each of said first and second surface projections have a base, said bases being~~the bases of at least two of said bone engaging structures are~~ adjacent to one another.

214. (currently amended) The spinal implant of claim 131, wherein each of said first and second surface projections have a base, said bases being~~said implant has a longitudinal axis and the bases of at least two adjacent bone engaging structures are~~ spaced apart from one another along a direction generally parallel to the mid-longitudinal~~ongitudinal~~ axis of said implant.

215. (currently amended) The spinal implant of claim 131, wherein each of said first and second surface projections have a base, said bases being~~said implant has a longitudinal axis and the bases of at least two adjacent bone engaging structures are~~ spaced apart from one another along a direction generally transverse to the mid-longitudinal~~ongitudinal~~ axis of said implant.

Claims 216-218 (cancelled).

219. (currently amended) An interbody spinal implant for insertion between adjacent vertebral bodies of a human spine, said implant comprising:

a leading end for introduction of said spinal implant into the spine, an opposite trailing end, ~~and~~ spaced apart sides therebetween, and a mid-longitudinal axis passing through said leading and trailing ends;

opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement in engagement with the bone of one of the vertebral bodies and said opposite lower surface adapted for

placement in engagement with the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

a plurality of surface projections~~bone engaging structures~~ formed on said upper and lower surfaces of said implant, at least a first and a second of said~~one of said bone engaging structures comprising~~ surface projections each~~projections~~ having at least one forward facing facet directed at least in part toward said leading end and at least one rearward facet directed at least in part toward said trailing end, each of said forward facet and rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, ~~said surface projections having opposed side facets directed generally toward said sides of said implant, said side facets located between said forward facet and said rearward facet of said surface projections, said side facets converging toward each other in a direction away from the base of said projections,~~ said first and second surface projections each~~rearward facet~~ having an included angle between said rearward facet and the base greater than 90 degrees relative to at least one of said upper and lower surfaces of said implant.

Claims 220-227 (cancelled).

228. (previously presented) The spinal implant of claim 219, wherein said upper and lower surfaces of said implant are at least in part arcuate.

229. (previously presented) The spinal implant of claim 219, wherein at least one of said leading end, trailing end, and sides are curved.

230. (previously presented) The spinal implant of claim 219, wherein said sides are curved.

231. (previously presented) The spinal implant of claim 219, wherein each of said leading end, trailing end, and sides are curved.

232. (previously presented) The spinal implant of claim 231, wherein said leading end, trailing end, and sides form a circle.

233. (previously presented) The spinal implant of claim 219, wherein said upper and lower surfaces of said implant are at least in part planar.

234. (currently amended) The spinal implant of claim 219, wherein said upper and lower surfaces converge toward each other along at least a portion of the length of said implant.

235. (previously presented) The spinal implant of claim 219, wherein said implant comprises a material other than bone.

236. (previously presented) The spinal implant of claim 219, wherein said implant comprises bone.

237. (previously presented) The spinal implant of claim 236, wherein said bone includes cortical bone.

238. (previously presented) The spinal implant of claim 219, wherein said implant comprises bone growth promoting material.

239. (previously presented) The spinal implant of claim 238, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

240. (previously presented) The spinal implant of claim 219, wherein said implant is treated with a bone growth promoting substance.

241. (previously presented) The spinal implant of claim 219, wherein said implant is a source of osteogenesis.

242. (previously presented) The spinal implant of claim 219, wherein said implant is at least in part bioabsorbable.

243. (previously presented) The spinal implant of claim 219, wherein said implant comprises metal.

244. (previously presented) The spinal implant of claim 243, wherein said metal includes titanium.

245. (previously presented) The spinal implant of claim 219, wherein said implant comprises at least one of a plastic material and a ceramic material.

246. (previously presented) The spinal implant of claim 219, wherein said implant is formed of a porous material and a material that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

247. (previously presented) The spinal implant of claim 219, wherein said implant is a motion preserving device adapted to space apart and allow motion between the adjacent vertebral bodies.

248. (previously presented) The spinal implant of claim 219, wherein said spinal implant is a fusion implant.

249. (currently amended) The spinal implant of claim 248, wherein said upper and lower surfaces include at least one opening to permit bone growth from ~~one of the~~ adjacent vertebral bodybodies to ~~the other one of the~~ adjacent vertebral bodybodies through said implant.

250. (previously presented) The spinal implant of claim 248, wherein said implant has an internal chamber and an access opening for accessing said internal chamber.

251. (currently amended) The spinal implant of claim 250, wherein said upper and lower surfaces include at least one opening in communication with said internal chamber to permit bone growth from ~~one of the~~ adjacent vertebral bodybodies to ~~the other one of the~~ adjacent vertebral bodybodies through said implant.

252. (previously presented) The spinal implant of claim 250, wherein said internal chamber is capable of containing bone growth promoting material.

253. (previously presented) The spinal implant of claim 252, wherein said bone growth promoting material is one of bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

254. (previously presented) The spinal implant of claim 219, further comprising at least one opening capable of retaining fusion promoting materials.

255. (currently amended) The spinal implant of claim 219, wherein said first and second surface projections each have a base, said bases being ~~the bases of at least two of said bone engaging structures are~~ adjacent to one another.

Claims 256-258 (cancelled).

259. (new) The spinal implant of claim 1, wherein said first and second surface projections each have opposed side facets directed generally toward said spaced apart sides of said implant, respectively, said side facets being located between said forward facet and said rearward facet of each of said first and second surface projections, said

side facets converging toward each other in a direction away from one of said upper and lower surfaces of said implant.

260. (new) The spinal implant of claim 259, wherein said opposed side facets intersect each other.

261. (new) The spinal implant of claim 260, wherein said opposed side facets converge to form a peak at the top of said surface projection.

262. (new) The spinal implant of claim 261, wherein said peaks of at least two of said surface projections are aligned along lines that are at least one of perpendicular, parallel, and diagonal to the mid-longitudinal axis of said implant.

263. (new) The spinal implant of claim 261, wherein said peak of said first surface projection overlies at least a portion of said second surface projection.

264. (new) The spinal implant of claim 261, wherein said peaks of said first and second surface projections are at the same height above one of said upper and lower surfaces of said implant.

265. (new) The spinal implant of claim 259, wherein adjacent side facets of adjacent surface projections are spaced apart to define a groove therebetween.

266. (new) The spinal implant of claim 259, wherein a plurality of adjacent surface projections are spaced apart to form a plurality of grooves therebetween.

267. (new) The spinal implant of claim 266, wherein at least one of said grooves is parallel to the mid-longitudinal axis of said implant.

268. (new) The spinal implant of claim 266, wherein at least two of said grooves cross each other.

269. (new) The spinal implant of claim 266, wherein at least one of said grooves has a horizontal cross-sectional shape that is one of a v-shape, u-shape, and a box-like shape.

270. (new) The spinal implant of claim 259, wherein each of said first and second surface projections have a base and said side facets have a maximum width therebetween at said base, said base being spaced apart from a base of another of said surface projections by a distance no greater than one-half the maximum width of one of said first and second surface projections.

271. (new) The spinal implant of claim 1, wherein said forward facets of each of said first and second surface projections face the same direction.

272. (new) The spinal implant of claim 131, wherein said first and second surface projections each have opposed side facets directed generally toward said leading and trailing ends, respectively, said side facets being located between said right facet and said left facet of each of said first and second surface projections, said side facets converging toward each other in a direction away from the base of each of said first and second surface projections.

273. (new) The spinal implant of claim 272, wherein adjacent side facets of adjacent surface projections are spaced apart to define a groove therebetween.

274. (new) The spinal implant of claim 272, wherein each of said first and second surface projections have a base and said side facets have a maximum width therebetween at said base, said base being spaced apart from a base of another of said surface projections by a distance no greater than one-half the maximum width of one of said first and second surface projections.

275. (new) The spinal implant of claim 272, wherein said opposed side facets converge to form a peak, said peaks of said first and second surface projections being at the same height above one of said upper and lower surfaces of said implant.

276. (new) The spinal implant of claim 131, wherein said right facets of each of said first and second surface projections face the same direction.

277. (new) The spinal implant of claim 219, wherein said surface projections have opposed side facets directed generally toward said sides of said implant, said side facets being located between said forward facet and said rearward facet of said surface projections, said side facets converging toward each other in a direction away from the base of said first and second projections.

278. (new) The spinal implant of claim 277, wherein said opposed side facets converge to form a peak at the top of each of said surface projections.

279. (new) The spinal implant of claim 278, wherein said peaks are aligned along lines that are at least one of perpendicular, parallel, and diagonal to the mid-longitudinal axis of said implant.

280. (new) The spinal implant of claim 277, wherein adjacent side facets of adjacent surface projections are spaced apart to define a groove therebetween.

281. (new) The spinal implant of claim 277, wherein a plurality of adjacent surface projections are spaced apart to form a plurality of grooves therebetween.

282. (new) The spinal implant of claim 281, wherein at least one of said grooves is parallel to the mid-longitudinal axis of said implant.

283. (new) The spinal implant of claim 281, wherein at least two of said grooves cross each other.

284. (new) The spinal implant of claim 281, wherein at least one of said grooves has a horizontal cross-sectional shape that is one of a v-shape, u-shape, and a box-like shape.

Amendments to the Drawings:

In response to the Examiner's request, the attached replacement sheets of formal drawings contain Figs. 1-24 and include the addition of Figs. 1A-1C, 12B, and 14A-C.

Attachment: 9 Replacement Sheets

REMARKS

Applicant cancelled claims 2, 4, 6-18, 132, 134, 136, 210-212, 216-218, 220-227, 249, 251, and 256-258; amended claims 1, 19, 20, 27, 45, 48, 56, 131, 133, 137, 141, 207-209, 213-215, 219, 234, and 255; and added new claims 259-284 to further define applicant's claimed invention. The amendment to claims 1, 19, and 20 is supported by the specification at least on page 13, line 5 to page 14, line 11 and Fig. 13. The amendment to claims 27, 141, and 234 is supported at least by Fig. 2. The amendment to claim 56 is supported at least by Fig. 20. The amendment to claims 131, 133, and 137 is supported at least by claims 131, 133, and 137, respectively, as originally filed. The amendment to claims 207, 213, and 255 is supported at least by Fig. 14. The amendment to claims 208, 209, 214, and 215 is supported in the specification at least on page 14, lines 2-4. The amendment to claim 219 is supported by the specification at least on page 13, line 5 to page 14, line 11 and Fig. 13. New claims 259 and 277 are supported at least by claim 1 as originally filed. New claims 260-262 are supported at least by claims 6-8 as originally filed. New claims 263, 264, 271, and 276 are supported at least by Fig. 13. New claims 265-269 are supported at least by claims 12-14, 17, and 18, respectively, as originally filed. New claims 270 and 274 are each supported at least by Figs. 12 and 15. New claim 272 is supported at least by claim 131 as originally filed. New claim 273 is supported at least by claim 12 as originally filed. New claim 275 is supported at least by claim 7 as originally filed and Fig. 13. New claims 278-284 are supported at least by claims 7, 8, 12-14, 17, and 18 as originally filed. No new matter has been added. New claims 259-284 read on species 3, Figs. 12-15.

Applicant also amended the drawings to include new Figs. 1A-1C, 12B, and 14A-C. New Fig. 1A is supported at least by Fig. 15 of U.S. Patent No. 5,593,409, which is incorporated by reference in the specification on page 7, lines 1 and 2. New Fig. 1B is supported at least by claim 25 as originally filed. New Fig. 1C is supported at least by claim 45 as originally filed. New Fig. 12B is supported at least by claim 131 as originally filed and Fig. 12A. New Figs. 14A and 14B is supported at least by claim 18 as

originally filed. New Fig. 14C is supported in the specification at least on page 4, lines 20 and 21. No new matter has been added.

In the Office Action, the Examiner rejected claims 1, 3, 5-15, 131, 133, 135-145, and 203-258 under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner objected to the phrase "bone engaging structure" in independent claims 1, 131, and 219. Applicant amended the claims to recite the phrase "surface projections" instead of "bone engaging structures."

The Examiner also objected to the terminology used in independent claim 131 to describe the orientation of the surface projections. Applicant amended claim 131 to recite a "right facet" and a "left facet" in place of a "forward facet" and a "rearward facet," respectively. As amended in claim 131, the right and left facets face the right and left sides, respectively, of the implant. Applicant submits that claims 1, 3, 5-15, 131, 133, 135-145, and 203-258 are definite.

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) as not showing every feature of the invention specified in the claims. In particular, the Examiner contended that the subject matter of claims 6, 8, 9-13, 15, 18, 21, and 131 were not illustrated. Applicant submits that one of ordinary skill in the art would understand the subject matter of the claims without the necessity of drawings. Nonetheless, in order to expedite prosecution, Applicant amended the drawings to include new Figs. 1A-C, 12B, and 14A-C, which show examples of an implant with upper and lower surfaces that are at least in part arcuate (claim 21); an implant where the leading end, trailing end, and sides form a circle (claim 25); an implant that is a motion preserving device (claim 45); an implant having a cap (claim 47); an implant having a right facet that has a longer length and a slope that is less steep than the slope of a left facet (claim 131); a U-shaped groove and a box-shaped groove (claim 269); and spaced apart surface projections (claim 265).

Applicant respectfully disagrees with the Examiner's contention with respect to the subject matter of claims 6 and 8 not being illustrated. Claim 6 recites opposed facets intersecting one another. The subject matter of claim 6 is found at least in Fig. 15, which shows side facets 332, 334 intersecting to form a peak 336. Claim 8 recites

that the peaks of at least two surface projections are aligned along lines that are "at least one of perpendicular, parallel, and diagonal" to the mid-longitudinal axis of the implant. An example of the peaks of at least two surface projections being aligned along perpendicular, parallel, or diagonal lines is found in Fig. 12A. In particular, peaks 326 are aligned along lines that are perpendicular to the mid-longitudinal axis (e.g., from the top to the bottom of the figure). Peaks 326 are also aligned parallel to the mid-longitudinal axis (e.g., from the left side to the right side of the figure). Peaks 326 are also aligned along a diagonal (e.g., from the right-top corner to the left-bottom corner of the figure). Accordingly, Applicant submits that the subject matter of claims 6 and 8 is illustrated in the drawings.

For claims 9-11 and 15, Applicant cancelled claims 9-11 and 15 in view of the amendment to claim 1 and the species elected in response to the Restriction Requirement of October 28, 2002.

For claims 12 and 13, Applicant added new Fig. 14C, which shows an example of surface projections with adjacent side facets of adjacent surface projections that are spaced apart to define a groove therebetween, and a plurality of surface projections being spaced apart to form a plurality of grooves therebetween.

For claim 21, Applicant added new Fig. 1A, which shows an example of an implant having upper and lower surface that are at least in part arcuate.

For claim 131, Applicant added new Fig. 12B, which shows an example of a left facet facing a left side of the implant and a right facet facing the right side of the implant.

Several of the elected claims include a recitation of a material or composition, or a combination of a material or composition (see, for example, claim 28). MPEP § 601.01(f) states that situations in which drawings are usually not considered necessary for the understanding of the invention under 35 U.S.C. 113 (first sentence) are: (A) Coated articles or products...[and] (B) Articles made from a particular material or composition..." (page 600-14, column 2 (August 2001)). Thus, Applicant submits that the claims that recite a material or composition, or combination thereof, do not require illustration.

It is submitted that the objection to the drawings under 37 C.F.R. § 1.83(a) has been overcome.

The Examiner rejected claims 1, 3, 5-15, 17-51, 131, 133, 135-145, and 303-258 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,482,233 to Aebi et al. Independent claim 1 as now amended recites an implant having a plurality of surface projections, at least a first and a second of the surface projections each having at least one forward facing facet and at least one rearward facing facet, "at least a portion of said rearward facet of said first surface projection overlying a portion of said forward facet of said second surface projection."

Aebi et al. teach an implant 10 having a plurality of spikes 28. (Aebi et al., col. 4, lines 53-54 and Figs. 1 and 6). Aebi et al. do not teach or suggest an implant having a plurality of surface projections as recited in independent claim 1.

Independent claim 131 as now amended recites an implant having a plurality of surface projections, at least a first and a second of the surface projections each having "at least one facet with the perimeter having at least a first and a second portion arranged to form an included angle greater than 90 degrees between said first and second portions." All of the facets taught by Aebi et al. have included angles of 90 degrees or less. (See, e.g., Aebi et al., Figs. 4, 6, and 7). Independent claim 131 also recites that the first and second surface projections each have "at least one right facet directed at least in part toward said right side and at least one left facet directed at least in part toward said left side, each of said right and left facets having a length and a slope, the length of said right facet being longer than the length of said left facet, the slope of said left facet being steeper than the slope of said right facet." Aebi et al. teach that "in the transverse direction, as shown in Fig. 7, the spikes are arranged in a regular "V" shape with each side of the spikes being at about the same angle as the other side." (Aebi et al., col. 4, lines 25-28). Aebi et al. do not teach or suggest an implant having a plurality of surface projections as recited in independent claim 131.

Independent claim 219 recites an implant having a plurality of surface projections, at least a first and a second of the surface projections each having "an included angle between said rearward facet and the base greater than 90 degrees

relative to at least one of said upper and lower surfaces of said implant." All of the facets taught by Aebi et al. have included angles of 90 degrees or less. (See, e.g., Aebi et al., Figs. 4, 6, and 7). Aebi et al. do not teach or suggest an implant having a plurality of surface projections as recited in independent claim 219.

Accordingly, Applicant submits that independent claims 1, 131, and 219 are allowable over the cited art and that dependent claims 3, 5-15, 133, 135-145, and 203-218, and 220-284 dependent from one of independent claims 1, 131, 219, or claims dependent therefrom are allowable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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